

IV. Remarks:

(i) Re: newly submitted Claims 4-10, and patentability in light of US 3,153,412 to Laubsch identified in Applicant's IDS dated September 8, 2005.

Previous claims 1-3 have been cancelled, and new claims 4-10 presented.

Newly presented independent method claim 4 and dependent claims 6 & 7 insofar as such depend from new claim 4, are each directed to a method of ultrasonic inspection of the testes of an adult patient, wherein a particular recited device for supporting the testes is utilized in carrying out such method.

In particular, newly presented method claim 4 now recites:

4. A method for inspecting and diagnosing ailments in human testes via ultrasonic inspection means, using a device comprising:

a pair of spaced-apart, downwardly curved members, each adapted to be positioned over a respective upper thigh portion of legs of a male patient and proximate a groin area of said patient when said patient is lying in a supine position;

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, adapted to raise and support thereon one or more male testes when said device is positioned proximate said groin area;

said method comprising:

positioning said male patient in said supine position;

placing said device in an operative position proximate said groin area of said patient, wherein each of said downwardly curved members each overlie said respective upper thigh portion of said legs of said patient;

positioning said testes of said male patient on said substantially flat portion of said device; and

ultrasonically inspecting said testes via said ultrasonic inspection means when said device is in said operative position and said testes positioned on said substantially flat portion.

Similarly, to like effect, newly presented claim 5 (and dependent claims 6 & 7 dependent therefrom) is directed to a method of use of a device ... during ultrasonic examination". In this regard, newly presented claim 5 recites as follows:

5. A method of use of a device for raising and supporting one or more testes of a patient during ultrasound examination when said patient is lying in a substantially supine position, said device comprising:

a pair of spaced-apart, downwardly curved members, each adapted to be positioned over a respective upper thigh portion of legs of a male patient and proximate a groin area of said patient when said patient is lying in a supine position;

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, adapted to raise and support thereon and intermediate said mutually opposite side edges one or more male testes when said device is positioned proximate said groin area;

said method of use comprising:

positioning said male patient in said supine position;

placing said device in an operative position proximate said groin area of said patient, wherein each of said downwardly curved members each overlie said respective upper thigh portion of said legs of said patient;

positioning said testes of said male patient on said substantially flat portion;
and

ultrasonically inspecting said testes via ultrasonic inspection means when said device is in said operative position and said testes positioned on said substantially flat portion.

Likewise, newly submitted apparatus claim 8 (and thus remaining dependent claims 9, 10 dependent therefrom) now expressly recites as follows:

8. A device for use in the inspecting and diagnosing ailments in human testes via ultrasonic inspection means, comprising:

a pair of spaced-apart, downwardly curved members, each adapted to be positioned over a respective upper thigh portion of legs of a male patient and proximate a groin area of said patient when said patient is lying in a supine position;

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, said flat portion adapted to raise and support thereon a pair of male testes when said device is positioned proximate said groin area to permit ultrasonic inspection of said testes when situate on said flat portion.

It is respectfully submitted each of the method and apparatus claims are patentably distinct over the device disclosed and taught in US 3,153,412 to Laubsch ("Laubsch") entitled "Scrotal Support".

To bluntly summarize the device disclosed in Laubsch, such device relates to a device whose primary purpose is to provide a supporting appliance which will hold the scrotum and genitalia of a male bedridden patient who is defecating while supine in a bedpan up above the area of fecal discharge, so as to avoid soiling of the scrotum and genitalia. As well, a further disclosed purpose of the Laubsch device is to drain urine from the forwardly projecting extension 2 into the bed pan (ref. col 2, line 30-32), presumably when the male patient, when bedridden in a supine position, is urinating (ref. Fig. 4 thereof).

For this purpose the extension 2 [of the generally concave supporting area 1-ref. col. 1, line 63-64 and Fig. 4] may be downwardly bent at 5 (ref. col 2, line 32-34 and Fig. 4. thereof), presumably to drain urine into the bedpan.

A further purpose, namely to "facilitate and render less painful the post-operative dressing of hydrocele (ie painless swelling of the scotum) and similar surgical cases" (ref. col. 1, lines 33-35), although further disclosed, is not anywhere further elaborated on or explained.

Importantly, nowhere in Laubsch is there ever disclosed or suggested that the scrotum support device of Laubsch may be used as part of an ultrasonic examination procedure to support the testes for ultrasonic examination thereof.

On the contrary, all that Laubsch suggests is merely the use of the device as a sanitary aid, to prevent soiling of the scrotum and genetalia during defecation.

It is respectfully submitted it would not be obvious to a person skilled in the art of personal hygiene products such as the device/product taught by Laubsch, to utilize the Laubsch device as part of a diagnostic procedure for ultrasonic examination of the testes (new claims 4-7), nor is the Laubsch device anticipatory or suggestive of the apparatus now recited in newly submitted apparatus claims 8-10.

Specifically, it would not be obvious to a person skilled in the art of personal hygiene products, such as that of Laubsch, who typically would comprise attending palliative care persons at hospitals and geriatric centers who would have no experience with ultrasonic examination procedures, to utilize such a personal hygiene device as taught in Laubsch, in an ultrasonic diagnostic examination procedure. On the contrary, responsibility for conducting ultrasonic procedures is typically conducted by a person of different skill, namely a medical lab technician, skilled in the art of ultrasonic examination equipment operation and procedures, who is responsible for providing ultrasonic images resulting

from such ultrasonic examination to an attending physician. There is no reason why such a medical lab technician would be familiar with personal hygiene products such as that taught by Laubsch, for it to be obvious to such a technician to incorporate a personal hygiene device in such procedure.

Moreover, however, and in any event, the personal hygiene product of Laubsch contains at least one structural feature that makes it unsuitable for use as part of the ultrasonic inspection method now claimed or as a device for ultrasonic inspection, as now claimed in newly submitted claims 4-7 and 8-10 respectively.

In this regard, Laubsch expressly teaches and specifically requires that the central supporting area 1 intermediate the two side wings 4,4 is **concave** (ie "a generally concave or depressed central supporting area" –ref. col 1, lines 54-55 and 63). This concave feature is for the purpose of draining of urine from the similarly concave forwardly projecting extension 2 which extends from the concave central supporting area 1 (ref. col. 2, lines 30-34, and Fig. 4 of Laubsch).

The particular device of Laubsch would not work in the method of the present invention for ultrasonic inspection of testes. In this regard, it is of importance that the device of the present invention as now claimed in all newly submitted claims possess a **substantially flat** portion (12) intermediate the two wing members (26a), (26b), to allow the person conducting the ultrasonic inspection to flatten the testes thereagainst during ultrasonic inspection thereof so as to permit individual ultrasonic inspection of each testes.

Such substantially flat portion (12) of the present invention distinguishes over the Laubsch device and is clearly and expressly now recited in each of newly submitted independent method claims 4, 5 and also in newly submitted independent apparatus claim 8 (and thus all claims of this application, as amended) as set out below:

Claim 4:

A method for inspecting and diagnosing ailments in human testes via ultrasonic inspection means, using a device comprising:

...

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, adapted to raise and support thereon one or more male testes when said device is positioned proximate said groin area;...

Claim 5:

A method of use of a device for raising and supporting one or more testes of a patient during ultrasound examination when said patient is lying in a substantially supine position, said device comprising:

...

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, adapted to raise and support thereon and intermediate said mutually opposite side edges one or more male testes when said device is positioned proximate said groin area;...

Claim 8:

A device for use in the inspecting and diagnosing ailments in human testes via ultrasonic inspection means, comprising:

...

a substantially flat portion, situate and extending intermediate said pair of curved members, having a pair of opposite, substantially mutually parallel side edges, said flat portion adapted to raise and support thereon a pair of male testes when said device is positioned proximate said groin area to permit ultrasonic inspection of said testes when situate on said flat portion.

By way of contrast, the concave central supporting area (1) of Laubsch, since it is expressly required to be concave and is not flat, would necessarily require the testes of a male patient to overly the other when placed thereon, thereby obstructing the ultrasonic inspection of each individual testes. This is expressly avoided in the method and device of the present invention by the specific provision/inclusion of a substantially flat portion intermediate the two

wing members to allow the person conducting the ultrasonic inspection to flatten the testes against such flat portion so as to permit individual ultrasonic inspection of each testes.

In addition, in a preferred embodiment with respect to the device of the present invention itself (as opposed to the method of use of the device of the present invention), to permit the wing members to better and more evenly rest on the thighs of male patients (so as to minimize motion of the device which is important to minimize in ultrasonic inspection imaging procedures), it is recited in newly submitted apparatus claim 6 that the radius of curvature of the wing members 26a, 26b proximate one side edge of the device is greater than the radius of curvature proximate the other side edge of the device. This is clearly shown in Fig. 1, and in the (better) side elevation view thereof of Fig. 3. In such manner the wing members 26 a, 26b of the device of the present invention may better and more closely conform to the radius of curvature of the thigh member of the patient which generally decreases moving in the direction toward the foot of the patient.

To this end, new claim 9 further recites this feature, namely:

Claim 9

The device of claim 8, wherein a radius of curvature of each of said downwardly curved portions proximate one of said mutually parallel side edges is greater than said radius of curvature of each of said downwardly curved portions proximate said other of said pair of mutually parallel side edges thereof.

Nowhere is this improvement ever taught or for that matter suggested for the device disclosed in Laubsch.

Lastly, by way of yet another preferred embodiment, newly amended claim 10 recites that the substantially flat planar area (12) of the device of the present invention may have one side edge of lesser length than the other, so as to effectively , when the device is properly positioned on the patient, better (and more comfortably) separate the legs of the patient allowing better access to an

attending tab technician or physician for the purposes of ultrasonic inspection of the testes. Such feature is clearly disclosed in the drawings on file (ref. Fig. 1 with respect to widths "W1" and "W2") alone or in combination with the disclosure, at page 8, lines 8-9 thereof.

In this regard, newly submitted claim 10 now recites this preferred embodiment of the device of the present invention as follows:

10. The device as claimed in claim 8 or 9, wherein a length of one of said opposite mutually parallel side edges of said flat portion is greater than a length of said other of said opposite mutually parallel side edges.

Nowhere is such feature ever taught or even remotely suggested in Laubsch.

In view of the above features/differences over Laubsch, it is respectfully submitted newly submitted method claims 4-7, and newly submitted apparatus claims 8-10, each contain inventive subject matter over Laubsch, and are patentably distinct thereover.

(ii) with respect to the amendments to the Specification

The specification has been amended to correct minor typographical errors appearing therein.

As well, a characterizing paragraph virtually identical to new claim 4 has been added to the summary of the invention, to more concisely summarize this particular aspect of the invention.

No other amendments have been made to the specification. No new subject matter has been added.

(iii) with respect to amendments to the Title

The title has been amended to more fully and correctly reflect the scope of the newly submitted claims now placed on file.

(iv) with respect to amendment to the Abstract

Minor amendments have been made to the Abstract to correct certain typographical errors contained therein, as may be seen from page 5 hereof.

(v) with respect to amendments to the Drawings

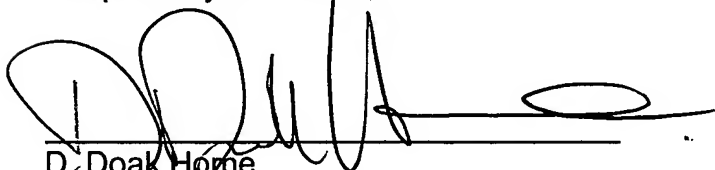
Fig. 3 previously on file, intended to be, as noted in the "Description of the Drawings", a "(rear) perspective view of the testicular support device shown in Fig. 1 taken in the direction of arrow 'A' " was not truly a rear perspective view of Fig. 1, and contained a number of inaccuracies. The correct rear perspective view of Fig. 1 is now shown in amended Fig. 3 enclosed herewith.

In making the corrections to Fig. 3 as noted above, no new subject matter has thereby been added.

(IV) Concluding Comments

Favorable consideration of this application, herein as amended, with a view to timely examination and allowance, is earnestly solicited.

Respectfully submitted,



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III. Amendments to the Drawings

Please replace drawing page containing Fig. 3 with new amended drawing page containing amended Fig. 3. The amendments made to Fig. 3 are addressed in the **REMARKS** Section of this Preliminary Amendment.

Attachment: Replacement Fig. 3